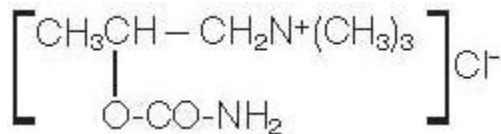


BETHANECHOL CHLORIDE - bethanechol chloride tablet

Caraco Pharmaceutical Laboratories, Ltd.

DESCRIPTION

Bethanechol chloride, a cholinergic agent, is a synthetic ester which is structurally and pharmacologically related to acetylcholine. It is designated chemically as 2-[(aminocarbonyloxy)-N, N, N-trimethyl- 1-propanaminium chloride. Its molecular formula is $C_7H_{17}ClN_2O_2$ and its structural formula is:



It is a white, hygroscopic crystalline powder having a slight amine-like odor, freely soluble in water, and has a molecular weight of 196.67.

Each tablet for oral administration contains 5 mg, 10 mg, 25 mg or 50 mg of bethanechol chloride, USP. Tablets also contain the following inactive ingredients: colloidal silicon dioxide, lactose anhydrous, magnesium stearate, microcrystalline cellulose, sodium starch glycolate and (25 mg and 50 mg) FD&C Yellow #6 aluminum lake.

CLINICAL PHARMACOLOGY

Bethanechol chloride acts principally by producing the effects of stimulation of the parasympathetic nervous system. It increases the tone of the detrusor urinae muscle, usually producing a contraction sufficiently strong to initiate micturition and empty the bladder. It stimulates gastric motility, increases gastric tone and often restores impaired rhythmic peristalsis.

Stimulation of the parasympathetic nervous system releases acetylcholine at the nerve endings. When spontaneous stimulation is reduced and therapeutic intervention is required, acetylcholine can be given, but it is rapidly hydrolyzed by cholinesterase and its effects are transient. Bethanechol chloride is not destroyed by cholinesterase and its effects are more prolonged than those of acetylcholine.

Effects on the GI and urinary tracts sometimes appear within 30 minutes after oral administration of bethanechol chloride, but more often 60 to 90 minutes are required to reach maximum effectiveness. Following oral administration, the usual duration of action of bethanechol is one hour, although large doses (300 to 400 mg) have been reported to produce effects for up to six hours. Subcutaneous injection produces a more intense action on bladder muscle than does oral administration of the drug.

Because of the selective action of bethanechol, nicotinic symptoms of cholinergic stimulation are usually absent or minimal when orally or subcutaneously administered in therapeutic doses, while muscarinic effects are prominent. Muscarinic effects usually occur within 5 to 15 minutes after subcutaneous injection, reach a maximum in 15 to 30 minutes, and disappear within two hours. Doses that stimulate micturition and defecation and increase peristalsis do not ordinarily stimulate ganglia or voluntary muscles. Therapeutic test doses in normal human subjects have little effect on heart rate, blood pressure or peripheral circulation.

Bethanechol does not cross the blood-brain barrier because of its charged quaternary amine moiety. The metabolic rate and mode of excretion of the drug have not been elucidated.

A clinical study (Diokno, A.C.; Lapidus, J.; *Urol* 10: 23-24, July 1977) was conducted on the relative effectiveness of oral and subcutaneous doses of bethanechol chloride on the stretch response of bladder muscle in patients with urinary retention. Results showed that 5 mg of the drug given subcutaneously stimulated a response that was more rapid in onset and of larger magnitude than an oral dose of 50 mg, 100 mg, or 200 mg. All the oral doses, however, had a longer duration of effect than the subcutaneous dose. Although the 50 mg oral dose caused little change in intravesical pressure in this study, this dose has been found in other studies to be clinically effective in the rehabilitation of patients with decompensated bladders.

INDICATIONS AND USAGE

Bethanechol chloride tablets are indicated for the treatment of acute postoperative and postpartum nonobstructive (functional) urinary retention and for neurogenic atony of the urinary bladder with retention.

CONTRAINDICATIONS

Hypersensitivity to bethanechol chloride tablets, hyperthyroidism, peptic ulcer, latent or active bronchial asthma, pronounced bradycardia or hypotension, vasomotor instability, coronary artery disease, epilepsy and parkinsonism.

Bethanechol chloride should not be employed when the strength or integrity of the gastrointestinal or bladder wall is in question, or in the presence of mechanical obstruction; when increased muscular activity of the gastrointestinal tract or urinary bladder might prove harmful, as following recent urinary bladder surgery, gastrointestinal resection and anastomosis, or when there is possible gastrointestinal obstruction; in bladder neck obstruction, spastic gastrointestinal disturbances, acute inflammatory lesions of the gastrointestinal tract, or peritonitis; or in marked vagotonia.

PRECAUTIONS

General

In urinary retention, if the sphincter fails to relax as bethanechol contracts the bladder, urine may be forced up the ureter into the kidney pelvis. If there is bacteriuria, this may cause reflux infection.

Information for Patients

Bethanechol chloride tablets should preferably be taken one hour before or two hours after meals to avoid nausea or vomiting. Dizziness, light-headedness or fainting may occur, especially when getting up from a lying or sitting position.

Drug Interactions

Special care is required if this drug is given to patients receiving ganglion blocking compounds because a critical fall in blood pressure may occur. Usually, severe abdominal symptoms appear before there is such a fall in the blood pressure.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Longterm studies in animals have not been performed to evaluate the effects upon fertility, mutagenic or carcinogenic potential of bethanechol chloride.

Pregnancy: Teratogenic Effects

Pregnancy Category C: Animal reproduction studies have not been conducted with bethanechol chloride. It is also not known whether bethanechol chloride can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Bethanechol chloride should be given to a pregnant woman only if clearly needed.

Nursing Mothers

It is not known whether this drug is secreted in human milk. Because many drugs are secreted in human milk and because of the potential for serious adverse reactions from bethanechol chloride in nursing infants, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

ADVERSE REACTIONS

Adverse reactions are rare following oral administration of bethanechol chloride, but are more common following subcutaneous injection. Adverse reactions are more likely to occur when dosage is increased.

The following adverse reactions have been observed: *Body as a Whole*: malaise; *Digestive*: abdominal cramps or discomfort, colicky pain, nausea and belching, diarrhea, borborygmi, salivation; *Renal*: urinary urgency; *Nervous System*: headache; *Cardiovascular*: a fall in blood pressure with reflex tachycardia, vasomotor response; *Skin*: flushing producing a feeling of warmth, sensation of heat about the face, sweating; *Respiratory*: bronchial constriction, asthmatic attacks; *Special Senses*: lacrimation, miosis.

Causal Relationship Unknown: The following adverse reactions have been reported, and a causal relationship to therapy with bethanechol has not been established: *Body as a Whole*: malaise; *Nervous System*: seizures.

OVERDOSAGE

Early signs of overdosage are abdominal discomfort, salivation, flushing of the skin ("hot feeling"), sweating, nausea and vomiting. *Atropine Sulfate* is a specific antidote. The recommended dose for adults is 0.6 mg. Repeat doses can be given every two hours, according to clinical response. The recommended dosage in infants and children up to 12 years of age is 0.01 mg/kg (to a maximum single dose of 0.4 mg) repeated every two hours as needed until the desired effect is obtained or adverse effects of atropine preclude further usage. Subcutaneous injection of atropine is preferred except in emergencies when the intravenous route may be employed. The oral LD₅₀ of bethanechol is 1510 mg/kg in the mouse.

DOSAGE AND ADMINISTRATION

Dosage must be individualized, depending on the type and severity of the condition to be treated.

Preferably give the drug when the stomach is empty. If taken soon after eating, nausea and vomiting may occur.

The usual adult oral dose ranges from 10 to 50 mg three or four times a day. The minimum effective dose is determined by giving 5 to 10 mg initially and repeating the same amount at hourly intervals until satisfactory response occurs, or until a maximum of 50 mg has been given. The effects of the drug sometimes appear within 30 minutes and are usually maximal within 60 to 90 minutes. The drug effects persist for about one hour.

If necessary, the effects of the drug can be abolished promptly by atropine (see **OVERDOSAGE**)

HOW SUPPLIED

Bethanechol Chloride Tablets, USP contains 5 mg, 10 mg, 25 mg or 50 mg of bethanechol chloride, USP and are supplied as follows:
5 mg: White to off-white, round, flat faced bevel edge, uncoated tablets, debossed with '137' on one side and scored on the other side.

NDC 57664-137-83 Bottles of 30 CRC
NDC 57664-137-88 Bottles of 100 CRC
NDC 57664-137-08 Bottles of 100 NCRC
NDC 57664-137-13 Bottles of 500 NCRC
NDC 57664-137-18 Bottles of 1000 NCRC

10 mg: White to off-white, round, flat faced bevel edge, uncoated tablets, debossed with '104' on one side and scored on the other side.

NDC 57664-104-83 Bottles of 30 CRC
NDC 57664-104-88 Bottles of 100 CRC
NDC 57664-104-08 Bottles of 100 NCRC
NDC 57664-104-13 Bottles of 500 NCRC
NDC 57664-104-18 Bottles of 1000 NCRC

25 mg: Light peach, round, flat faced bevel edge, uncoated tablets, debossed with '138' on one side and scored on the other side.

NDC 57664-138-83 Bottles of 30 CRC
NDC 57664-138-88 Bottles of 100 CRC
NDC 57664-138-08 Bottles of 100 NCRC
NDC 57664-138-13 Bottles of 500 NCRC
NDC 57664-138-18 Bottles of 1000 NCRC

50 mg: Light Peach, round, flat faced bevel edge, uncoated tablets, debossed with '106' on one side and scored on the other side.

NDC 57664-106-83 Bottles of 30 CRC
NDC 57664-106-88 Bottles of 100 CRC
NDC 57664-106-08 Bottles of 100 NCRC
NDC 57664-106-13 Bottles of 500 NCRC
NDC 57664-106-18 Bottles of 1000 NCRC

Dispense in a tight container as defined in the USP.

Store at 20 - 25°C (68 - 77°F). (See USP Controlled Room Temperature).

Manufactured by: Sun Pharmaceutical Industries, Inc.

Cranbury, NJ 08512

Distributed by: Caraco Pharmaceutical Laboratories, Ltd.

Detroit, MI 48202

December 2008

Stock No. 6052T01

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL- 5 MG 30 TABLETS

NDC 57664-137-83

Bethanechol Chloride Tablets, USP

5 mg

Rx Only

30 Tablets



PACKAGE LABEL.PRINCIPAL DISPLAY PANEL- 5 MG 100 TABLETS

NDC 57664-137-88

Bethanechol Chloride Tablets, USP

5 mg

Rx Only

100 Tablets

NDC 57664-137-88

Bethanechol Chloride Tablets, USP

5 mg

Rx Only
100 Tablets



Each tablet contains 5 mg of bethanechol chloride, USP.

USUAL DOSAGE: Read package insert. Dispense in a tight container as defined in the USP.

Store at 20 - 25°C (68 - 77°F). (See USP Controlled Room Temperature).

This package is not intended for dispensing.

S. No. 6059L01 Iss. 11/08

Dist. by: Caraco Pharmaceutical Laboratories, Ltd.
Detroit, MI 48202

Mfg. by: Sun Pharmaceutical Industries, Inc.
Cranbury, NJ 08512



LOT NO.:
EXP. DATE:

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL- 5 MG 100 TABLETS

NDC 57664-137-08

Bethanechol Chloride Tablets, USP

5 mg

Rx Only


100 Tablets

NDC 57664-137-08

Bethanechol Chloride Tablets, USP

5 mg

Rx Only
100 Tablets



Each tablet contains 5 mg of bethanechol chloride, USP.

USUAL DOSAGE: Read package insert. Dispense in a tight container as defined in the USP.


Store at 20 - 25°C (68 - 77°F). (See USP Controlled Room Temperature).

This package is not intended for dispensing.

S. No. 6060L01 Iss. 11/08

Dist. by: Caraco Pharmaceutical Laboratories, Ltd.
Detroit, MI 48202

Mfg. by: Sun Pharmaceutical Industries, Inc.
Cranbury, NJ 08512



LOT NO.:
EXP. DATE:

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL- 5 MG 500 TABLETS

NDC 57664-137-13

Bethanechol Chloride Tablets, USP

5 mg

Rx Only

500 Tablets

NDC 57664-137-13

Bethanechol Chloride Tablets, USP

5 mg

Rx Only
500 Tablets



Each tablet contains 5 mg of bethanechol chloride, USP.

USUAL DOSAGE: Read package insert. Dispense in a tight container as defined in the USP.

Store at 20 - 25°C (68 - 77°F). (See USP Controlled Room Temperature).

This package is not intended for dispensing.

S. No. 6086L01 Iss. 11/08

Dist. by: Caraco Pharmaceutical Laboratories, Ltd.
Detroit, MI 48202

Mfg. by: Sun Pharmaceutical Industries, Inc.
Cranbury, NJ 08512



LOT NO.:
EXP. DATE:

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL- 5 MG 1000 TABLETS

NDC 57664-137-18

Bethanechol Chloride Tablets, USP

5 mg

Rx Only

1000 Tablets

NDC 57664-137-18

**Bethanechol
Chloride
Tablets, USP**

5 mg

Rx Only
1000 Tablets



Each tablet contains 5 mg of bethanechol chloride, USP.

USUAL DOSAGE: Read package insert.
Dispense in a tight container as defined in the USP.
Store at 20 - 25°C (68 - 77°F). (See USP Controlled Room Temperature).
This package is not intended for dispensing.

S. No. 6087L01 Iss. 11/08
Dist. by: Caraco Pharmaceutical Laboratories, Ltd.
Detroit, MI 48202
Mfg. by: Sun Pharmaceutical Industries, Inc.
Cranbury, NJ 08512

 N 3 57664 13718 5

LOT NO.:
EXP. DATE:

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL- 10 MG 30 TABLETS

NDC 57664-104-83

Bethanechol Chloride Tablets, USP

10 mg

Rx Only

30 Tablets

NDC 57664-104-83

**Bethanechol
Chloride
Tablets, USP**

10 mg

Rx Only
30 Tablets



Each tablet contains 10 mg of bethanechol chloride, USP.

USUAL DOSAGE: Read package insert.
Dispense in a tight container as defined in the USP.
Store at 20 - 25°C (68 - 77°F). (See USP Controlled Room Temperature).

S. No. 6088L01 Iss. 11/08
Dist. by: Caraco Pharmaceutical Laboratories, Ltd.
Detroit, MI 48202
Mfg. by: Sun Pharmaceutical Industries, Inc.
Cranbury, NJ 08512

 N 3 57664 10483 5

LOT NO.:
EXP. DATE:

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL- 10 MG 100 TABLETS

NDC 57664-104-88

Bethanechol Chloride Tablets, USP

10 mg

Rx Only

100 Tablets

NDC 57664-104-88

Bethanechol Chloride Tablets, USP

10 mg

Rx Only
100 Tablets



Each tablet contains 10 mg of bethanechol chloride, USP.

USUAL DOSAGE: Read package insert. Dispense in a tight container as defined in the USP.

Store at 20 - 25°C (68 - 77°F). (See USP Controlled Room Temperature).

This package is not intended for dispensing.

S. No. 6057L01 Iss. 11/08

Dist. by: Caraco Pharmaceutical Laboratories, Ltd.
Detroit, MI 48202

Mfg. by: Sun Pharmaceutical Industries, Inc.
Cranbury, NJ 08512



LOT NO.:
EXP. DATE:

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL- 10 MG 100 TABLETS
NDC 57664-104-08
Bethanechol Chloride Tablets, USP
10 mg
Rx Only
100 Tablets

NDC 57664-104-08

Bethanechol Chloride Tablets, USP

10 mg

Rx Only
100 Tablets



Each tablet contains 10 mg of bethanechol chloride, USP.

USUAL DOSAGE: Read package insert. Dispense in a tight container as defined in the USP.

Store at 20 - 25°C (68 - 77°F). (See USP Controlled Room Temperature).

This package is not intended for dispensing.

S. No. 6058L01 Iss. 11/08

Dist. by: Caraco Pharmaceutical Laboratories, Ltd.
Detroit, MI 48202

Mfg. by: Sun Pharmaceutical Industries, Inc.
Cranbury, NJ 08512



LOT NO.:
EXP. DATE:

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL- 10 MG 500 TABLETS
NDC 57664-104-13
Bethanechol Chloride Tablets, USP
10 mg
Rx Only
500 Tablets

NDC 57664-104-13

Bethanechol Chloride Tablets, USP

10 mg

Rx Only
500 Tablets



Each tablet contains 10 mg of bethanechol chloride, USP.

USUAL DOSAGE: Read package insert. Dispense in a tight container as defined in the USP.

Store at 20 - 25°C (68 - 77°F). (See USP Controlled Room Temperature).

This package is not intended for dispensing.

S. No. 6089L01 Iss. 11/08

Dist. by: Caraco Pharmaceutical Laboratories, Ltd.
Detroit, MI 48202

Mfg. by: Sun Pharmaceutical Industries, Inc.
Cranbury, NJ 08512



LOT NO.:
EXP. DATE:


PACKAGE LABEL.PRINCIPAL DISPLAY PANEL- 10 MG 1000 TABLETS
NDC 57664-104-18
Bethanechol Chloride Tablets, USP
10 mg
Rx Only
1000 Tablets

NDC 57664-104-18

**Bethanechol
Chloride
Tablets, USP**

10 mg

Rx Only
1000 Tablets


 **SUN**
PHARMACEUTICAL
INDUSTRIES, INC.

Each tablet contains 10 mg of bethanechol chloride, USP.

USUAL DOSAGE: Read package insert.
Dispense in a tight container as defined in the USP.
Store at 20 - 25°C (68 - 77°F). (See USP Controlled Room Temperature).

This package is not intended for dispensing.

S. No. 6090L01 **Iss. 11/08**
Dist. by: **Caraco Pharmaceutical Laboratories, Ltd.**
Detroit, MI 48202
Mfg. by: **Sun Pharmaceutical Industries, Inc.**
Cranbury, NJ 08512

 N 3 57664 104 18 7

LOT NO.:
EXP. DATE:

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL- 25 MG 30 TABLETS
NDC 57664-138-83
Bethanechol Chloride Tablets, USP
25 mg
Rx Only
30 Tablets

NDC 57664-138-83

**Bethanechol
Chloride
Tablets, USP**

25 mg

Rx Only
30 Tablets

 **SUN**
PHARMACEUTICAL
INDUSTRIES, INC.

Each tablet contains 25 mg of bethanechol chloride, USP.

USUAL DOSAGE: Read package insert.
Dispense in a tight container as defined in the USP.

Store at 20 - 25°C (68 - 77°F). (See USP Controlled Room Temperature).

S. No. 6091L01 **Iss. 11/08**
Dist. by: **Caraco Pharmaceutical Laboratories, Ltd.**
Detroit, MI 48202
Mfg. by: **Sun Pharmaceutical Industries, Inc.**
Cranbury, NJ 08512

 N 3 57664 138 83 0

LOT NO.:
EXP. DATE:

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL- 25 MG 100 TABLETS
NDC 57664-138-88
Bethanechol Chloride Tablets, USP
25 mg
Rx Only
100 Tablets

NDC 57664-138-88

Bethanechol Chloride Tablets, USP

25 mg

Rx Only
100 Tablets



Each tablet contains 25 mg of bethanechol chloride, USP.

USUAL DOSAGE: Read package insert. Dispense in a tight container as defined in the USP.

Store at 20 - 25°C (68 - 77°F). (See USP Controlled Room Temperature).

S. No. 6056L01 Iss. 11/08

Dist. by: Caraco Pharmaceutical Laboratories, Ltd.
Detroit, MI 48202

Mfg. by: Sun Pharmaceutical Industries, Inc.
Cranbury, NJ 08512



LOT NO.:
EXP. DATE:

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL- 25 MG 100 TABLETS

NDC 57664-138-08

Bethanechol Chloride Tablets, USP

25 mg

Rx Only

100 Tablets

NDC 57664-138-08

Bethanechol Chloride Tablets, USP

25 mg

Rx Only
100 Tablets



Each tablet contains 25 mg of bethanechol chloride, USP.

USUAL DOSAGE: Read package insert. Dispense in a tight container as defined in the USP.

Store at 20 - 25°C (68 - 77°F). (See USP Controlled Room Temperature).

This package is not intended for dispensing.

S. No. 6055L01 Iss. 11/08

Dist. by: Caraco Pharmaceutical Laboratories, Ltd.
Detroit, MI 48202

Mfg. by: Sun Pharmaceutical Industries, Inc.
Cranbury, NJ 08512



LOT NO.:
EXP. DATE:

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL- 25 MG 500 TABLETS

NDC 57664-138-13

Bethanechol Chloride Tablets, USP

25 mg

Rx Only

500 Tablets

NDC 57664-138-13

Bethanechol Chloride Tablets, USP

25 mg

Rx Only
500 Tablets



Each tablet contains 25 mg of bethanechol chloride, USP.

USUAL DOSAGE: Read package insert. Dispense in a tight container as defined in the USP.

Store at 20 - 25°C (68 - 77°F). (See USP Controlled Room Temperature).

This package is not intended for dispensing.

S. No. 6092L01 Iss. 11/08

Dist. by: Caraco Pharmaceutical Laboratories, Ltd.
Detroit, MI 48202

Mfg. by: Sun Pharmaceutical Industries, Inc.
Cranbury, NJ 08512



LOT NO.:
EXP. DATE:

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL- 25 MG 1000 TABLETS

NDC 57664-138-18

Bethanechol Chloride Tablets, USP

25 mg

Rx Only

1000 Tablets

NDC 57664-138-18

Bethanechol Chloride Tablets, USP

25 mg

Rx Only
1000 Tablets



Each tablet contains 25 mg of bethanechol chloride, USP.

USUAL DOSAGE: Read package insert. Dispense in a tight container as defined in the USP. Store at 20 - 25°C (68 - 77°F). (See USP Controlled Room Temperature).

This package is not intended for dispensing.

S. No. 6093L01 Iss. 11/08

Dist. by: Caraco Pharmaceutical Laboratories, Ltd.
Detroit, MI 48202

Mfg. by: Sun Pharmaceutical Industries, Inc.
Cranbury, NJ 08512

 57664 13818 2

LOT NO.:
EXP. DATE:

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL- 50 MG 30 TABLETS

NDC 57664-106-83

Bethanechol Chloride Tablets, USP

50 mg

Rx Only

30 Tablets

NDC 57664-106-83

Bethanechol Chloride Tablets, USP

50 mg

Rx Only
30 Tablets



Each tablet contains 50 mg of bethanechol chloride, USP.

USUAL DOSAGE: Read package insert. Dispense in a tight container as defined in the USP.

Store at 20 - 25°C (68 - 77°F). (See USP Controlled Room Temperature).

S. No. 6094L01 Iss. 11/08

Dist. by: Caraco Pharmaceutical Laboratories, Ltd.
Detroit, MI 48202

Mfg. by: Sun Pharmaceutical Industries, Inc.
Cranbury, NJ 08512

 57664 10683 9

LOT NO.:
EXP. DATE:

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL- 50 MG 100 TABLETS

NDC 57664-106-88

Bethanechol Chloride Tablets, USP

50 mg

Rx Only

100 Tablets

NDC 57664-106-88

Bethanechol Chloride Tablets, USP

50 mg

Rx Only
100 Tablets



Each tablet contains 50 mg of bethanechol chloride, USP.

USUAL DOSAGE: Read package insert. Dispense in a tight container as defined in the USP.

Store at 20 - 25°C (68 - 77°F). (See USP Controlled Room Temperature).

S. No. 6054L01 **Iss. 11/08**

Dist. by: Caraco Pharmaceutical Laboratories, Ltd.
Detroit, MI 48202

Mfg. by: Sun Pharmaceutical Industries, Inc.
Cranbury, NJ 08512



LOT NO.:
EXP. DATE:

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL- 50 MG 100 TABLETS

NDC 57664-106-08

Bethanechol Chloride Tablets, USP

50 mg

Rx Only


100 Tablets

NDC 57664-106-08

Bethanechol Chloride Tablets, USP

50 mg

Rx Only
100 Tablets



Each tablet contains 50 mg of bethanechol chloride, USP.

USUAL DOSAGE: Read package insert. Dispense in a tight container as defined in the USP.


Store at 20 - 25°C (68 - 77°F). (See USP Controlled Room Temperature).

This package is not intended for dispensing.

S. No. 6053L01 **Iss. 11/08**

Dist. by: Caraco Pharmaceutical Laboratories, Ltd.
Detroit, MI 48202

Mfg. by: Sun Pharmaceutical Industries, Inc.
Cranbury, NJ 08512



LOT NO.:
EXP. DATE:

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL- 50 MG 500 TABLETS

NDC 57664-106-13

Bethanechol Chloride Tablets, USP

50 mg

Rx Only

500 Tablets

NDC 57664-106-13

Bethanechol Chloride Tablets, USP

50 mg

Rx Only
500 Tablets



Each tablet contains 50 mg of bethanechol chloride, USP.

USUAL DOSAGE: Read package insert. Dispense in a tight container as defined in the USP.

Store at 20 - 25°C (68 - 77°F). (See USP Controlled Room Temperature).

This package is not intended for dispensing.

S. No. 6095L01 **Iss. 11/08**

Dist. by: Caraco Pharmaceutical Laboratories, Ltd.
Detroit, MI 48202

Mfg. by: Sun Pharmaceutical Industries, Inc.
Cranbury, NJ 08512



LOT NO.:
EXP. DATE:


PACKAGE LABEL-PRINCIPAL DISPLAY PANEL- 50 MG 1000 TABLETS
NDC 57664-106-18
Bethanechol Chloride Tablets, USP
50 mg
Rx Only
1000 Tablets

NDC 57664-106-18

**Bethanechol
Chloride
Tablets, USP**

50 mg

Rx Only
1000 Tablets


SUN
PHARMACEUTICAL
INDUSTRIES, INC.

Each tablet contains 50 mg of bethanechol chloride, USP.

USUAL DOSAGE: Read package insert.
Dispense in a tight container as defined in the USP.
Store at 20 - 25°C (68 - 77°F). (See USP Controlled Room Temperature).

This package is not intended for dispensing.

S. No. 60961.01 Iss. 11/08
Dist. by: Caraco Pharmaceutical
Laboratories, Ltd.
Detroit, MI 48202
Mfg. by: Sun Pharmaceutical Industries, Inc.
Cranbury, NJ 08512


N 3 57664 10618 1

LOT NO.:
EXP. DATE: